

SOP-DM-003	CTN-DSC URINE TRACKING PROCEDURE	Date Approved:
Approved by:	Date Revised: Revised by:	Page 1 of 1

1. Request that the Shipping Log be modified to capture CTN specified information (see attached file). Urine Number (type of test required) may not be needed, but could possibly be required depending upon the nature of the protocol.
2. Request that the site (CTP) fax a copy of the shipping log to their Data Management Group at the time of shipping the data to Northwest Toxicology (NWT).
3. Request that NWT fax a copy of the shipping log WITH ACCESSION NUMBER to the CTP's Data Management Group at the time of receipt.
- 4a. If possible, add Sample Number (a bar coded label number that gets placed on the urine sample) to the information collected on a Urine Log (CTN Urine Log Form 205 for Bup). The Urine Log is Subject Specific, while the Shipping Log is not necessarily Subject specific. In addition, the Urine Log contains "visit" information (Study Week/Study Day/ some identifier used for the protocol) and who collected/shipped the urine samples.
- 4b. Related to this, NWT would need to provide each CTP with 4 identical bar coded labels for 1) Urine sample sent to NWT, 2) Backup Urine Sample, 3) Log sent to NWT, and 4) Log sent to each node's Data Management Center).
5. The results of the assays should be FAXED to the CTPs at each participating node, with a hard copy to follow in the mail to the Data Management Groups (I believe this is the process identified for the Bup protocol. For blinded studies, the FAX should NOT be sent to the CTPs).
6. An electronic copy of the results should be sent at a pre-determined interval (e.g., weekly, monthly, immediately following each shipment) to the Data Management Groups for the data from their CTPs. The key point here being that the electronic data is sent on a REGULAR schedule.
7. Discrepancies should be resolved according to the Data Management Processes in place at each participating node. HOWEVER, any modifications to the electronic copies should be sent to Northwest Toxicology as an "FYI" so that they are aware of changes that needed to be made to the data they supplied. This is to ensure that Northwest does not have a different copy of the data than that at each node.